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Date

Name

Robert L. Stone



Docket: Sa-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: NAINA SACHDEV

Serial No.: 10/630,184

Group Art Unit: 1616

Filed: July 30, 2003

Examiner: Frank I. Choi

For: ANTI-WRINKLING COMPOSITION AND AGE REVELAL COMPLEX

Mail Stop: Non-Fee Amendment

Commissioner for Patents

P.O. Box. 1450

Alexandria, VA 22313-1450

Honorable Commissioner for Patents:

DECLARATION UNDER 37 CFR 1.132

My name is Chimpamma Potini.

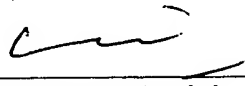
1. I am Vice President for Research and Development of HNC Products, Inc., of Clinton, Illinois. HNC Products, Inc. is engaged, *i. a.* in development of cosmetic and pharmaceutical products and I am responsible for the evaluation and development of such products.
2. I have the degree of Master of Science in Chemistry from Texas A&M University in 1978.
3. I have a consultant business relationship with Dr. Naina Sachdev of Lake Oswego, Oregon to assist in the development of her invention of an alkaline composition for reducing, preventing and/or removing skin wrinkles that contains carnosine.
4. I am familiar with Dr. Sachdev's patent application Serial No. 10/630,184 and its publication as Pub. No. 2004/0057974 and have been advised of the Office Action of December 27, 2004, that has been sent in that application.
5. I was asked to review US Patent 6,358,514 to Boussouira and evaluate its disclosure in comparison with Dr. Sachdev's patent application.
6. The Boussouira patent discloses a composition containing retinoid and histidine derivative to treat *i. a.* skin against aging. Histidine derivative is shown to improve the effectiveness of the retinoid.
7. In Example 1 of the patent retinoid stability was determined in a series of comparisons A-J with water/ethanol (40/60%) solvent and 0.3% all-trans retinol at 45°C and 55% R.H.. In Comparisons A and B only retinoid was used at pH 8 and 11, respectively and no stability of retinoid was found after 7 and 15 days. In comparison C, 0.1% of carnosine was added at pH 8.2 and the stability was initially 17% at 7 days and only 4% at 15 days. Instead of carnosine 0.1% of various histidine derivatives were added at acidic pH 5.5 for Composition C and differing alkaline pH values (8.2, 11 and 12) and, except for Composition I at pH 8.2, all tests at alkaline pH revealed substantial retinoid stability (44% to 78% after 7 days and 10% to 63% after 15 days. It was concluded that "for a comparable pH, carnosine stabilizes

retinol much less than the histidine derivatives used according to the invention." (col. 11, lines 16-18)

8. I was asked to evaluate the stability of alkaline compositions containing carnosine, with and without retinol, under conditions similar to those reported in the Boussouira patent, except using larger amounts of carnosine than 0.1% which was unsuccessfully used by Boussouira. The compositions and the results are set forth on Exhibit 1, attached hereto.
9. As shown on the first page of Exhibit 1 Compositions 1, 2 and 3 contained a hydro/alcoholic solvent with a 3:2 ratio of alcohol to water solvent and 0.30% of Retinol-50C. They also contained 1.00%, 5.00% and 20.00%, respectively of carnosine and were at pH 8.00, 8.20 and 8.20 respectively. Compositions 4, 5 and 6 were similar except that they were aqueous based and did not contain alcohol. The pH values for these compositions were all 8.50.
10. The results for the Hydro/Alcoholic and Aqueous Base Formulations are tabulated on the second page of Exhibit 1. The percentage recoveries of carnosine were determined for each formula after one week at room temperature and at an elevated temperature. Although not shown on the Exhibit page, the relative humidity for the room temperature tests was 60% and the elevated temperature was 40°C and with 75% relative humidity.
11. The results obtained with greater amounts of carnosine than used unsuccessfully in the Boussouira patent revealed substantial recovery and stability for carnosine in all of the carnosine/retinol compositions ranging 26% to 84% for the hydro/alcoholic based formulations at room temperature and 26% to 86% at elevated temperature and 40% to 94% for the aqueous based formulations at room temperature and 40% to 93% at elevated temperature.
12. Based upon the results obtained, carnosine at concentrations greater than that used with retinol in the Boussouira patent retained substantial stability. This was quite unexpected since the Boussouira patent found that carnosine should not be used with retinol.
13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be

true, and further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under 18 U.S. C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2-28-05
Date


Chimpamma Potini

Exh 1
r.)



	<u>Alcohol / water 60/40</u>			<u>Water</u>		
	<u>HNC 137-24</u>					
<u>Ingredient % w/w</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>
Ethyl Alcohol	59.25	56.70	47.7	-	-	-
Water	39.30	37.85	31.85	98.55	94.55	79.55
Retinol-50C	0.30	0.30	0.30	0.30	0.30	0.30
Dimethyl MEA	0.15	0.15	0.15	0.15	0.15	0.15
L-Carnosine	1.00	5.00	20.00	1.00	5.00	20.00
<u>Physical</u>	Clear Solution	Clear Solution	Suspension	Hazy --solution	Hazy --solution	Clear --solution
<u>PH (Neat)</u>	8.00	8.20	8.20	8.50	8.50	8.50

L-Carnosine Assay values attached with this report

Ex. 1
B2



L-Carnosine Assay Results Tabulated

Hydro/ Alcoholic Formulations(%)

	<u>Initial</u>	<u>One week</u>	
		<u>25/60</u>	<u>40/75</u>
1.00	1.00	0.50	0.50
5.00	3.00	1.30	1.30
20.00	20.00	16.70	17.30

Aqueous Base Formulations(%)

1.00	1.00	0.40	0.40
5.00	6.00	3.90	3.80
20.00	20.00	18.70	18.60

Percentage Recoveries After One Week

	<u>CRT</u>	<u>Elevated</u>
Formula 1	50	50
Formula 2	26	26
Formula 3	84	86
Formula 4	40	40
Formula 5	78	76
Formula 6	94	93

6/17/04